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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
19 August 2004 (19.08.2004)

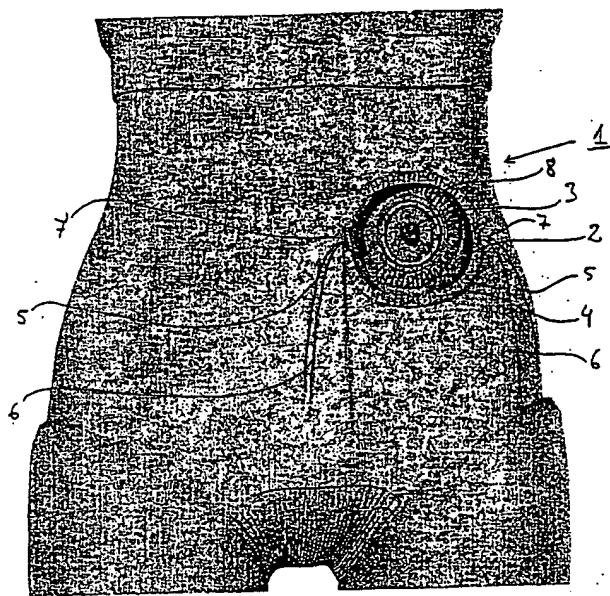
PCT

(10) International Publication Number
WO 2004/069118 A1

- (51) International Patent Classification: **A61F 5/449**
- (21) International Application Number:
PCT/DK2004/000075
- (22) International Filing Date: 3 February 2004 (03.02.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
PA 2003 00143 3 February 2003 (03.02.2003) DK
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lebæk (DK).
- (81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,
KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,
MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG,
PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM,
ZW.
- (84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), Euro-
pean (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,
GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).
- Published:
— with international search report

[Continued on next page]

(54) Title: AN OSTOMY SUPPORT GARMENT



(57) Abstract: An ostomy support garment in the form of a material having a hole for receiving a stoma, said hole having a stabilised edge wherein the edge is provided with an element allowing an increase or reduction of the length of the edge of the hole and providing a snug fit to the stoma ensures an easy application and removal of the garment and of a collecting bag combined with a sufficient support next to the stoma.

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TITLE

An Ostomy Support Garment

BACKGROUND OF THE INVENTION**5 1. Field of the Invention**

The present invention relates to an ostomy support garment having a hole for receiving a stoma and more particularly to an ostomy support garment having an adjustable hole for receiving a stoma.

- 10 In connection with surgery for a number of diseases in the gastrointestinal tract a consequence is, in many cases that the colon, the ileum or the urethra has been exposed surgically and the patient is left with an abdominal stoma. Such artificial openings or fistulae cannot be controlled at will and are therefore of necessity incontinent and the effluents or waste products of the body, which are conveyed
- 15 through these organs, are discharged through the artificial orifice or opening and are collected in a collection bag. Said bag is usually adhered to the skin by means of an adhesive wafer or plate having an inlet opening for accommodating the stoma. Such appliances may be two-piece or one-piece appliances. In both types of appliances, a body side member is attached to the wearer's abdomen,
- 20 and a receiving member or bag is attached to the body side ostomy member for receiving exudates from the stoma. Said receiving member being attached releasably in case of a two-piece appliance.

- In many instances patients having had a surgery resulting in the formation of a
- 25 stoma, an accompanying condition is formation of a peristomal bulge or hernia, which may complicate the bandaging of the stoma and even require further surgery. Even if further surgery is carried out there is a considerable risk of a permanent condition, which cannot be alleviated.

- 30 In such cases, the patient will have to rely on an additional hernia support for a mechanical reposition of the bulge or hernia for reducing the risk of constriction or strangulation calling for urgent surgery and for providing a plane surface around

the stoma for application of a collecting appliance in order to secure a proper adherence and sealing. Stomal bulge or hernia supports are commonly known and may e.g. be in the form of a belt of e.g. of leather with buckles or in the form of a support garment made from an elastic fabric being able to apply a sufficient pressure around the stoma.

In the case of a colostomy and in case the ostomate is normally irrigating, a minor cap or collecting bag may be used which enables the use of a firm support belt or tight compression briefs for providing a sufficient pressure around the stoma. For ileostomates or urostomates this procedure is not practicable due to the constant rather high output from the ileum or bladder and for urostomates it may be critical to provide a free flow from the stoma in order to prevent a build-up of a backpressure, which may destroy the kidneys.

In such cases, it is highly desirable or mandatory to give access to a larger collecting volume, which means that the collecting bag itself will have to be situated outside the pressure establishing belt or briefs and that a passageway through the same has to be established.

Determination of the site for placing the stoma is normally carried out prior to the operation after observing the patient in different postures, e.g. sitting, standing and bending over, finding the less critical area. WO 00/67683 discloses a device for use in the determination of the optimum position of a stoma-to-be for the patient in question.

As the placing of a stoma is not standardised but depends on the condition and the topography of the abdominal area of the patient, it is not possible to provide a simple selection of standard bulge or hernia supports fitting the majority of patients. The passageways must be tailored according to the actual conditions of the individual patient.

When making a hole in an ostomy support garment it has to be considered that the supporting effect of the missing material has to be provided for in another way and furthermore, it is necessary to stabilise the edge of a hole in order to avoid that it is inadvertently enlarged. At the same time, the effect of the stretching of the support garment and deformation of the shape of the hole when applied has to be taken into consideration as well as the problems associated with providing a sufficiently large hole for allowing an easy passing of an ostomy collection bag during application and removal of the garment and the passing of intestinal contents from the stoma into the bag and at the same time providing a sufficiently snug fit to the stoma to ensure the support next to the stoma.

2. Description of the Related Art

DK Patent Application No. PA 1999 01559 discloses a stomal hernia support compression garment in the form of a pair of compression trousers having a customised hole. The edge of the hole is stabilised by incorporation of a string of nylon sewn with a lockstitch and a zigzag stitch to ensure that the shape of the hole is not changed and furthermore, an enforcement of cotton is sewn using zigzag stitch for stabilising the area around the hole.

US 5,135,520 discloses a variable closure device for an ostomy garment having a pair of criss-cross pocket forming panels configured to lie behind an ostomy device. The criss-cross arrangement of pocket panels are created by finished edges which overlap along their lower ends to define an adjustable, elongated, slanted slot.

It is an object of the present invention to provide a hernia supporting device which provides a hole through which an ostomy bag may be passed, but which is shaped such that the bag is not moved out of the hole by accident. Thus it is an object to provide a hole with an unbroken edge.

It is also an object of the present invention to provide a hole which is flexible so as to make it easier for the user to pass the ostomy bag through the hole and such that the hole adapts to the shape of the ostomy device.

- 5 Additionally it is an object of the present invention to provide a supporting device that has an inner surface which is as smooth as possible, such that it does not irritate the skin it is pressed against. Thus it is an object of the present invention to provide no or as few seams or overlapping materials as possible.

10 **SUMMARY OF THE INVENTION**

The present invention relates to an ostomy support garment having a hole for receiving a stoma, said hole having a stabilised and adjustable edge.

Brief Description of the Drawings

- 15 The invention is disclosed more in detail with reference to the drawings in which Figure 1 shows an embodiment of the invention in the form of a pair of support briefs worn by a user. Figs. 2-7 show different configurations of the cord arrangement and garment.

20 **Detailed Description of the Present Invention**

- The present invention relates to an ostomy support garment in the form of a material having a hole for receiving a stoma, said hole having a stabilised edge wherein the edge is provided with an element allowing an increase or reduction of the length of the edge of the hole and wherein the element is a cord placed in a
25 passage at the edge of the hole.

- It may be seen as an advantage of the present invention that the hole (and its edge) is provided in one piece which is both flexible and stable enough to support the ostomy bag. Had the edge of the hole been inflexible it would be harder to
30 pull the ostomy bag through the hole, as the hole could not be temporarily enlarged. Furthermore an unflexible hole could not follow the movement of the user and thus an edge of the hole would apply unwanted pressure to the ostomy

bag for some positions of the user e.g. when sitting down or when bending forward.

5 It may further be seen as an advantage of the present invention that the surface surrounding the hole is provided as *one* piece of material whereby seams and overlapping elements are avoided. By avoiding such seams and overlaps the risk of irritation of the skin of the user is minimised.

10 By changing the effective length of the edge of the hole, the size of the hole may be temporarily increased and/or the shape of the hole may be temporarily changed for facilitating the application or removal of the garment or a collecting bag. By length of the edge of the hole is meant the length of the perimeter of the hole i.e. the distance along the inner edge of the hole. The cross-sectional area of the hole may be bigger by increasing the length of the edge. However for the
15 same length of the edge of the hole, the cross-sectional area may vary as a circular hole has bigger area than an elliptic hole.

As the hole is defined by the flexibility of the garment material and the adjustability of the cord element, the cross-sectional shape of the hole may be
20 changed by the user. E.g. the user may pull one zone of the edge in one direction and thus provide an oval shape of the hole. Due to the flexible nature of the garment the inner shape of the hole will adapt to the outer shape of the ostomy bag and thus provide a snug fit between the bag and/or a coupling provided on the bag and the hernia supporting device.

25 The use of a passage in the edge of the hole stabilises said edge and allows for a continuous adaptation of the length of the edge of the hole. The passage may extend along the entire edge of the hole or may be divided into a plurality of passages distributed along the edge. If a plurality of passages are provided it
30 may be easier for the user to replace a broken cord as the user need not to mingle a cord through a long passage without being able to pull the cord most of

the way. On the other hand a continuous cord provides the best fit between the device and the ostomy bag.

5 The garment of the invention has a hole having a stabilised edge being sufficiently stiff and providing a snug fit to the stoma to ensure a sufficient support next to the stoma and also enabling an easy application and removal of the garment or a collecting bag.

10 The supporting device of the present invention may be mass-produced in different sizes and with different positions of the hole. However the best fit is provided by customising the device and the hole the user of the device. Such customisation makes it possible to provide an even closer fit between the edge of the hole and the ostomy bag as the hole is positioned in the exactly the right spot.

15 In one embodiment the garment of the invention is made from an elastic material and the element is a string attached to the edge in a manner allowing an increase or decrease of the perimeter of the hole. When tightening the string, a snug adaptation of the size of the hole to the stoma is obtained together with a
20 sufficient support next to the stoma and when loosening the string, an enlargement of the size of the hole is obtained which facilitates the application and removal of the garment or a collecting bag.

25 In one preferred embodiment of the invention the element is forming a lace giving the option of a simple fixation of the length by tying a knot or bow or by locking the ends of the cord using a cord lock when the ends of the cord have a common exit from the passage. This embodiment gives a simple loosening and fixation of the cord(s) and adaptation of the length of the rim of the hole, especially for users having poor dexterity.

30 In another preferred embodiment of the invention the element is in the form of two cords having two common exits from the passage, preferably situated spaced

about 180° from each other, the cords passing through complementary parts of the passage and each set of two ends of the cords having the common exits from the passage being locked using a cord lock.

- 5 In an alternative embodiment, the element is an elastic element which together with the elasticity of the material from which the garment is made allows for a temporary enlargement of the hole without having to rely on untying and tying a string or lace. An elastic element is suitably an elastic band such as a band of rubber, cord fabric, or cavalry twill.

- 10 In a further embodiment of the invention the garment has a hole, which is provided with a slit, which juts from the edge of the hole into the material, and the element is a fastening element enabling a closure of the slit reducing the perimeter of the hole. When removing the fastening element temporarily, the hole
15 may easily be enlarged and obtain a keyhole shape facilitating the application and removal of the garment or a collecting bag. Then, the fastening element is repositioned closing the slit and providing a snug fit to the stoma and a sufficient support next to the stoma. In this embodiment, the increase or reduction of the length is not depending on elasticity of the material from which the garment is
20 made. Thus, also non-elastic materials may be used without jeopardizing the facility of the application and removal of the garment or a collecting bag.

- In this embodiment, the fastening is an element closing the slit is suitably a lace placed in a passage at the edge of the hole, said passage being interrupted by
25 the slit. When untying the lace, the hole may be enlarged and obtain a keyhole shape and the size of the hole is reduced by tying a knot or bow drawing the ends of the passage together providing a snug fit to the stoma.

- In the alternative, the fastening closing the slit is a zip-like fastener drawing the
30 edges of the slit together or snaps, buckles, buttons, rings or by mating elements of hook and loop fastening material bridging the slit at the edge of the hole.

If the fastenings closing the slit are able to take up the stretching forces of the garment when applied, the slit may stretch from the edge of the hole to the waste-line of the garment facilitating the application and removal of the garment.

5 Description of the Preferred Embodiments

The invention is now explained more in detail with reference to the drawings showing preferred embodiments of the invention.

Reference is made to Figure 1 showing an embodiment of an ostomy support garment of the invention in the form of a pair of support briefs **1** worn by a user, said briefs having a hole **2** for receiving a stoma **3**, said hole having a stabilised edge **4** wherein the edge is in the form of a passage in which are placed two cords **5,6** leaving the passage through two common exits from the passage situated spaced about 180° from each other, each of the cords passing through complementary parts of the passage and each set of two ends of the cords having common exits from the passage being locked using a cord lock **7,7'**. An ostomy body side member **8** is placed on the abdomen of the user for attachment of a collecting bag.

Figs. 2-6 show different configurations of cords. In fig. 2 a first cord **10** and a second cord **12** are each attached to a point of attachment **14**. The cords together encircle the hole **2** with the stabilised edge **4**. In the embodiment of the figure the cords encircle the entire hole, but in other embodiments the cords may encircle only a part of the hole **2**. Each cord is tightened by means of a cord fastener **16** having a spring biased rod **18** adapted to secure the cord. In the figure the cords each encircle one half of the hole **2**. However in other embodiments the cords may encircle different shares of the hole. E.g. one may encircle one quarter while the other encircles three quarters. In the configuration of fig. 3 only a first cord **10** is provided. The cord encircles the entire hole **2** and is tightened by means of a cord fastener **16**. In fig. 4 the hole **2** is encircled by a first cord **10** and a second cord **12**. Two cord fasteners **18** are provided and each are adapted to tighten an end of the first cord **10** and an end of the second cord **12**.

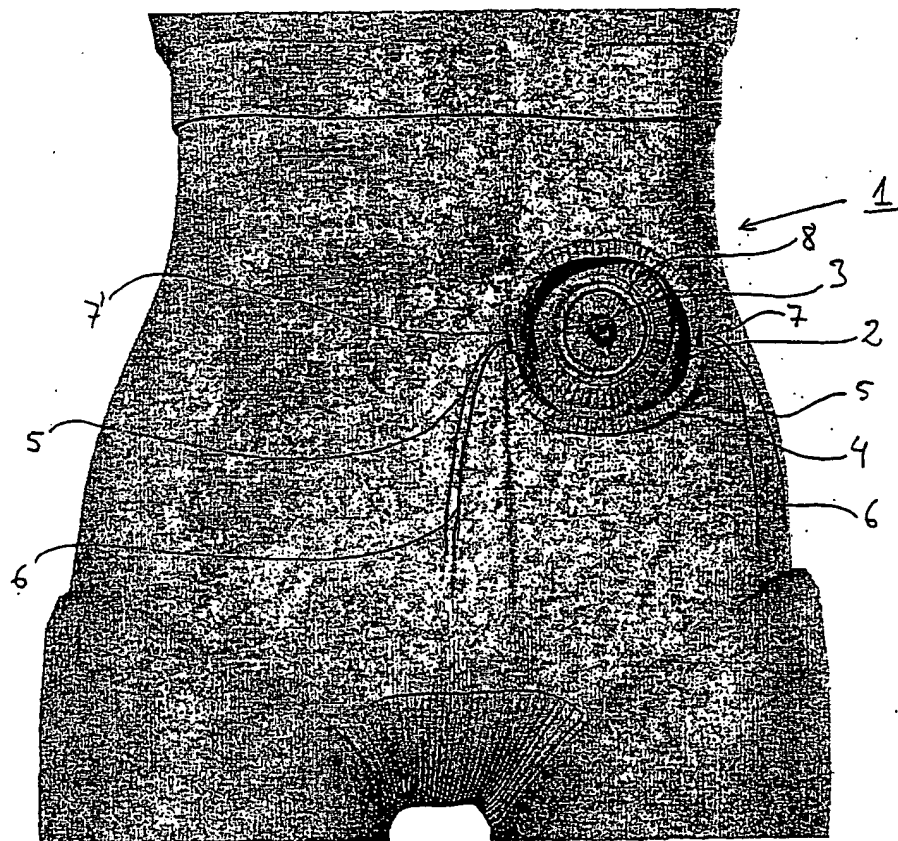
The configuration of fig. 5 is related to the configuration of fig. 3 but with two cords – a first cord **10** and a second cord **12** – being provided. The first cord **10** is provided closer to the stabilised edge **4** than the second cord **12**. In fig. 6 a first cord **10** is provided in an 8-shape. Thus the user of the device may close the hole
5 by pulling the free part of the 8-shape in opposite directions **20** and **22**. The tightened cord may be released from the cord fastener **18** by means of the rod **18**.

In fig. 7 a garment is provided with two holes, each for one stoma. The holes
10 have stabilised edges and may be fastened by means of first cord **10** and second cord **12** and their respective cord fasteners **16**.

Claims

1. An ostomy support garment in the form of a material having a hole for receiving a stoma, said hole having a stabilised edge wherein the edge is provided with an element allowing an increase or reduction of the length of the edge of the hole and wherein the element is a cord placed in a passage at the edge of the hole.
5
2. A garment as claimed in claim 1 wherein the garment is made from an elastic material and the element is a string attached to the edge in a manner allowing an increase and decrease of the perimeter of the hole.
10
3. A garment as claimed in claim 1 wherein the element is a lace.
4. A garment as claimed in claim 1 wherein the element is an elastic element.
15
5. A garment as claimed in claim 4 wherein the element is an elastic band, cord fabric, or cavalry twill.
6. A garment as claimed in claim 1 wherein the hole is provided with a slit, which juts from the edge of the hole into the material and the element is a fastening element enabling a closure of the slit reducing the perimeter of the hole.
20
7. A garment as claimed in claim 6 wherein the fastening is an element closing the slit is a lace placed in a passage at the edge of the hole, said passage being interrupted by the slit.
25
8. A garment as claimed in claim 6 wherein the fastening is an element closing the slit is a zip-like fastener, snaps, buckles, buttons, rings or by mating elements of hook and loop fastening material bridging the slit at the edge of the hole.
30

Fig. 1



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Fig. 2

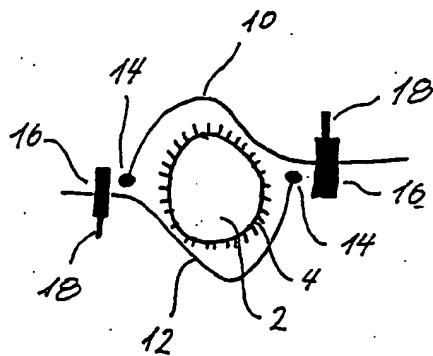


Fig. 3

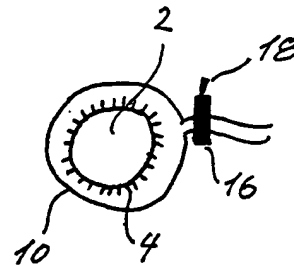


Fig. 4

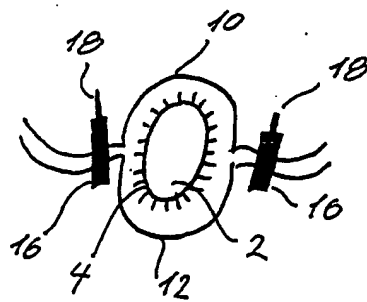


Fig. 5

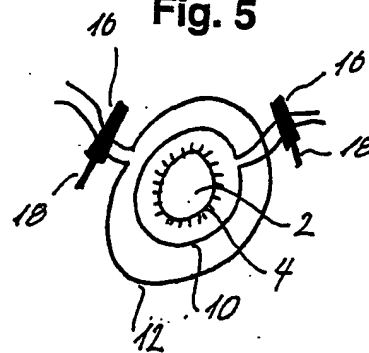


Fig. 6

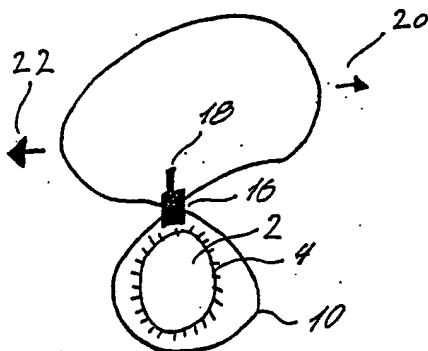


Fig. 7

